

Application Serial No. 10/522,322
Reply to Office Action of March 4, 2010

PATENT
Docket: CU-4060

REMARKS

In the Office Action, dated March 4, 2010, the Examiner states that Claims 33-63 are pending and rejected. By the present Amendment, Applicant amends the claims.

Claim Objections

The claims are objected to because the Office Action considers that they include duplicates or substantial duplicate claims that are so close in content that they both cover the same thing. In this respect, Claims 33 and 34 are noted in the Office Action, as well as Claims 35-63. Applicant respectfully disagrees with and traverses this objection.

The Office Action alleges that Claims 33 and 34 would cover the same thing despite a difference in wording. In particular, the Examiner considers the phrases (i) "an extract of a mixture of herbs" and (ii) "a mixture of herb extracts" as equivalent or substantial duplicates, i.e. identical in composition.

Applicant has reviewed and considered, from an analytical and chemical standpoint, the assertions in the Office Action, and now comes to a technically substantiated conclusion. It is correct and also reflected in the instant specification that both phrases may indeed be deemed being in some way or the other equivalent. However, equivalent in this context does not necessarily mean identical or substantially identical in composition and/or taste.

The chemical composition of (i) an extract of a mixture of herbs pertains to an extract produced by extracting all herbs in one single extraction medium. Here the herbs will be extracted in the same extract solvent under the exact same conditions such a pH, solvent composition, temperature, extraction time, etc. In addition, the presence of different herbs, possibly in different amounts, has an influence for the resulting composition, too. Compounds from one herb can influence extraction of compounds from other herbs. There can be interactions and the concentrations of individual compounds can differ due to shifts in extraction equilibrium.

The chemical composition of (ii) a mixture of herb extracts is a mixture of previously produced extracts. Each extract can be the result of different extraction conditions, e.g. herb/solvent ratio, temperature, solvent type, extraction time, etc.

Hence, a mixture of herb extracts will always differ in composition from an extract of an herb mixture. While compositions of (i) and (ii) may be equivalent in

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one or more aspects, they will always differ on the molecular level.

In order to reflect this molecular difference in composition, Claims 33 and 34 were phrased to complement each other and not to duplicate each other.

The same line of argument applies to the objections to Claims 35/36 and further to those claims depending on Claims 33 and 36 listed on page 3 of the office action in the 2nd and 3rd paragraphs. Also, the same line of argument applies to the three methods of Claims 61 to 63, which will result in confectionery articles evidently having different chemical compositions.

Finally, Applicant notes that new Claim 64 has been added. In analogy to the above arguments for the difference of Claims 33 and 34 as well as Claims 35 and 36, it is clear that the confectionery article will differ in composition from the compositions of the confectionery articles of Claims 33 and 34 as well as Claims 35 and 36, even though it may be equivalent in some other aspects.

In view of the foregoing, Applicant respectfully requests withdrawal of the objections to the claims.

Rejections under 35 U.S.C. §112

Claims 33-60 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Applicant has amended independent Claims 33-36 such that they recite the transitional phrase "consisting essentially of" or "consist essentially of" as opposed to the phrase "consisting of." In using the transitional phrase "consisting essentially of," the claims are interpreted to include all of the stated features as well as additional features (or ingredients) that do not affect the basic and novel characteristics of the claimed invention(s).

For example, Claim 33 is directed to a confectionery article in non liquid form consisting essentially of herbal mixtures, where the herbal mixtures consist essentially of an extract of a mixture of herbs and an extract of *Stevia rebaudiana* wherein the herbs are peppermint, sage, yarrow and thyme. Claim 37 is directed to the confectionery article as claimed in claim 33, where the herbal mixtures further consist of at least one of the herbs selected from the group consisting of lemon balm, common plantain, marshmallow, lady's mantle, elder, cowslip, anise, speedwell, mallow and horehound. Applicant respectfully asserts that the foregoing ingredients

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recited in Claim 37 are properly dependable from Claim 33 because if combined with the article recited in Claim 33, they would not materially affect the basic and novel characteristics of the invention recited in Claim 33. The same line of reasoning is applied to the remaining claims that were rejected under 35 U.S.C. §112, second paragraph, and as such, withdrawal of these rejections is respectfully requested.

Rejections under 35 U.S.C. §103(a)

Claims 33-52 and 57-60 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kirschner et al. (US 6,352,713) in view of Zhao (US 2002/0132037), Teranishi et al. (JP 57068772) and Kano et al. (JP 09194370). Claims 53-56 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kirschner in view of Zhao and Yotka et al. (WO 91/03147). Claims 61-63 are rejected under 35 U.S.C. §103(a) as being unpatentable over Oppenheimer et al. (US 4,980,169) in view of Teranishi (JP 57068772), Kirschner (US 6,352,713) and Zhao (US 2002/0132037). Applicant respectfully disagrees with and traverses these rejections.

At the outset, Applicant notes that in order to support a *prima facie* case of obviousness, the Office Action must establish "a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference." Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in view of *KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57,526 (Oct. 10, 2007). Applicant will explain hereinafter that the prior art, taken alone or in combination, does not teach each and every feature of the currently pending independent claims. Since the prior art does not teach or suggest each and every feature of the presently claimed invention as defined in the independent claims, Applicant respectfully asserts that a *prima facie* case of obviousness cannot presently be established.

First of all, Applicant respectfully asserts that none of the prior art teaches or suggests a confectionery article in non-liquid form consisting essentially of an herb extract of (or a mixture of herb extracts of) peppermint, sage, yarrow and thyme as well as Stevia extract. Moreover, Applicant respectfully asserts that the disclosures of each of the cited prior art documents teach additional ingredients or method steps that are not included by the present independent claims due to the transitional

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phrase "consisting essentially of." The additional method steps and/or ingredients taught in connection with the disclosures of the prior art documents would affect the basic and novel characteristics of the claimed invention(s) and as such, are excluded from the currently pending independent claims.

Applicant notes that Kirschner teaches a chewable nutritional tablet composition featuring a vitamin C/vitamin B9 (folic acid) combination together with glycyrrizin as sweetener (see claim 1 in column 20) or together with an anti-nausea agent (see claim 2 in column 20). From claims 2 and 3 it is evident that vitamin C and vitamin B are so distasteful and even irritant that addition of an anti-nausea agent or sweetener for oral nutritive formulations can become necessary. Additionally, it is very generally mentioned that further biologically active substance may be present (col. 13, 14-23) and that herbs can be added, in this respect referring to more than a hundred different herbs as examples (col. 13, l. 24-60).

Applicant respectfully asserts that Kano teaches the blending of a sweetener combination of Stevia extract and a sugar alcohol with an unpleasant tasting food beverage comprising vitamin C and vitamin Bs in order to render the vitamin composition more acceptable for oral consumption.

Teranishi teaches sweetening carbonated drinking water with Stevia extract.

Yattka teaches an encapsulated chewing gum and a delayed stevioside sweetener, i.e. with the sweetening molecule isolated from Stevia.

Zhou discloses a sweetener composition that is approx. 8 times as sweet as refined sugar (see [0018]) and which is composed of an isolated terpene glycoside, e.g. from Stevia (claim 9), together with at least one of glucose, fructose and maltose (claim 1).

Oppenheimer teaches a confection for oral dissolution comprising a volatile oil, e.g. peppermint, together with a volatile oil-modifying agent that is sensorially undetected in the amounts present but modifies the sensory perception of said volatile oil (claim 1). As optional sweetener component the isolated compound stevioside of Stevia is mentioned (col. 6, l. 45).

Applicant respectfully asserts that Kirschner is irrelevant for assessing patentability of the present invention because it is limited to the concept of sweetening the obnoxious taste of vitamins C and B by adding glycyrrin. It thus requires ingredients that are excluded by the currently pending claims. It is further

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taught that biologically active substances and probably any (non-toxic) herb can be added for taste or actively.

Kano solves the problems of the same distasting vitamin composition already taught by Kirschner by adding a combination of Stevia and a sugaralcohol. Evidently, Kano does not consider Stevia alone as sufficiently sweet.

Teranishi and Yattka have in common that they use Stevia extract or isolated stevioside for sweetening carbonated drinking water or chewing gum, respectively.

Zhou informs the skilled person in the art that a terpene glycoside such as the one derived from Stevia extract requires further sugars to provide for a naturally tasting refined sugar substitute.

In summary, the contribution of the documents of Kirschner, Kano, Teranishi and Yattka does not teach beyond the sweetening use of stevioside or Stevia extract sweetener for vitamin, food and drink compositions.

With regard to Oppenheimer, it seems that the Office Action has mischaracterized the disclosure of this reference. Oppenheimer teaches an orally dissolving confection with a volatile oil and a sensorial undetected amount of an agent for modifying the perception of the volatile oil. It may also comprise a sweetener such as stevioside (col. 6, l 45).

First of all, in the context of volatile oils, stevioside is clearly taught as a sweetener and not as volatile-oil modifying agent. This understanding is evident because a sweetener must be present in an amount sufficient to sweeten. If stevioside was intended as volatile oil-modifying agent, it would have to be present in sensorically undetected amounts. As for volatile-modifying agents, Oppenheimer's disclosure is limited to capsicum compounds, i.e. chilli and pepper components with extreme potency of bite, pungency, characteristic odor and burning effects in the throat (see col. 7, lines 20-51 and both examples). It is also noted that Claim 1 of the US patent is lacking an essential feature of the invention of Oppenheimer, that is volatile oil-modifying agent is capsicum oleoresin. This deficiency is clear in view of the absence of any other options for the volatile oil-modifying agent and confirmed by claim 2, which depends on Claim 1 and refers to the presence of "said capsicum oleoresin."

In short, the relevant disclosure content of Oppenheimer reads on a confectionery article for oral dissolution with a bitter or unpleasant taste due to

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volatile ingredients, e.g. from menthol, eucalyptus, peppermint, etc. that is modified by addition of a sensorically undetected amount of capsicum oleoresin and which may comprise sweeteners such as stevioside, which must be present in an amount leading to a sweet(er) taste.

According to Claim 33 the non-liquid confectionery article of the invention consists essentially of 5 herb extracts, i.e. peppermint, sage, yarrow, thyme and stevioside extracts. The effect is that the overall taste perception of all 5 components changes. The result is not just a further sweet stevioside perception added to the 4 remaining taste components, but an unexpected change in every one of the 4 remaining taste components without repressing these tastes by superimposition of sweetness. A good example of such an effect would seem to be the addition of sugar to tomato sauce to produce ketchup or spaghetti sauce. The substantial amount of sugar in ketchup and spaghetti sauce intensifies and modifies the tomato flavor without making it sweet.

As such, Applicant respectfully asserts that one of ordinary skill in the art following Oppenheimer's directions would only consider steviosides or Stevia extract a means for sweetening bitter confectionery articles, which is in line with the teachings of Kano, Teranishi and Yattka for vitamin pills, food and drink. In view of these teachings the skilled person would have expected only a sweetening effect with adding steviosides or Stevia extract to peppermint, sage, yarrow and thyme extracts. For modifying any bitter taste in a peppermint, sage yarrow and thyme extract, the skilled person would have reverted to the addition of a sensorically non-detectable amount of capsicum oleoresin, as taught in Oppenheimer.

In summary, it seems that the Office Action has hitherto applied an impermissible hindsight-directed approach for interpreting the prior art with the knowledge of the invention in mind. Moreover, the prior art references include features that are excluded by the currently pending claims and thus cannot properly be cited as rendering the presently claimed invention(s) obvious. Finally, as noted above, the prior art references, taken alone or in combination, do not teach or suggest each and every feature of the currently pending independent claims and as such, a *prima facie* case of obviousness cannot presently be established. Therefore, withdrawal of the present rejections under 35 U.S.C. §103(a) is respectfully requested.

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In light of the foregoing response, all the outstanding objections and rejections are considered overcome. Applicant respectfully submits that this application should now be in condition for allowance and respectfully requests favorable consideration.

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Date

Respectfully submitted,



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